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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.            |
|---|-------------|----------------------|---------------------------------|-----------------------------|
| 10/599,914  | 10/13/2006  | Yaping Shou          | PU60813 PCT/US                  | 6553                        |
| 20462 7590 04/06/2009<br>SMITHKLINE BEECHAM CORPORATION<br>CORPORATE INTELLECTUAL PROPERTY-US, UW2220<br>P. O. BOX 1539<br>KING OF PRUSSIA, PA 19406-0939 |             |                      | EXAMINER<br>WOOD, AMANDA P      |                             |
|   |             |                      | ART UNIT<br>1657                | PAPER NUMBER                |
|   |             |                      | NOTIFICATION DATE<br>04/06/2009 | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US\_cipkop@gsk.com

# Office Action Summary

**Application No.**

10/599,914

**Applicant(s)**

SHOU ET AL.

**Examiner**

AMANDA P. WOOD

**Art Unit**

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/55/08)  
Paper No(s)/Mail Date 1/07, 8/07, 10/08
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

### **DETAILED ACTION**

Claims 1-23 are presented for consideration on the merits.

#### ***Information Disclosure Statement***

The information disclosure statements (IDS) submitted on 12 January 2007, 16 August 2007, and 9 October 2008 have been considered by the examiner, and an initialed and signed/dated copy is included with this Office Action.

#### ***Drawings***

The drawings submitted by Applicant on 16 March 2006 have been accepted by the Examiner.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thirkettle et al (J. Antibiotics 2000) in view of Kosaka et al (Clin. Chim. Acta 2000), as cited by Applicant in the IDS dated 12 January 2007.

A method is claimed for determining inhibition of Lp-PLA2 enzyme activity in at least one sample.

Thirkettle et al teach an assay method wherein LpPLA2 was assayed in 96 well microplates using a plate reader. Thirkettle et al teach that the LpPLA2 enzyme and then the substrate (i.e., 1-Decanoyl-2-(p-nitrophenylglutaryl)phosphatidylcholine, also known as DNPG). Thirkettle et al also teach that reactions were also carried out with 10 minutes pre-incubation of inhibitor with enzyme prior to substrate addition (see, for example page 665, col. 1).

Thirkettle et al do not expressly teach a method wherein the sample is a blood or serum sample.

Kosaka et al beneficially teach a spectrophotometric assay method for serum platelet-activating factor acetylhydrolase (i.e., Lp-PLA2) wherein human serum is used as the sample. Kosaka et al further beneficially teach that the PAF analogue 1-Myristoyl-2-(4-nitrophenylsuccinyl)phosphatidylcholine is synthesized and used as substrate in the assay method, In addition to other PAF analogues with 4-nitrophenyl groups. Kosaka et al teach that the 1-Myristoyl-2-(4-nitrophenylsuccinyl)phosphatidylcholine substrate was about five times more specific for serum PAH-AH than previously reported substrates (see, for example, page 155).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods disclosed by Thirkettle et al, based upon the beneficial teachings provided by Kosaka et al, with respect to the teaching of a novel substrate for Lp-PLA2 activity assays, as discussed above. Furthermore, Kosaka et al beneficially teach that the substrate demonstrated in the assay is five times more specific for serum Lp-PLA2, and therefore it would have been both obvious and

beneficial for one of skill in the art to use the substrate provided by Kosaka et al in the methods of Thirkettle et al. The result-effective adjustment of particular conventional working conditions (e.g., using particular amounts of assay reagents and/or administering inhibitor at particular time points prior to or during an enzyme inhibition assay) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

### ***Conclusion***

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA P. WOOD whose telephone number is (571)272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

APW  
Examiner  
Art Unit 1657

/Lisa J. Hobbs/  
Primary Examiner, Art Unit 1657